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JOHN S. BEULICK C/O ARMSTRONG TEASDALE, LLP			SHARON, AYAL I		
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Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)			
	10/064,191	PAPPONE, DANIEL			
Office Action Summary	Examiner	Art Unit			
	Ayal I. Sharon	2123			
The MAILING DATE of this communication appeariod for Reply	pears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
<u> </u>	s action is non-final.				
	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.				
Disposition of Claims					
4) ☐ Claim(s) 1-15 is/are pending in the application 4a) Of the above claim(s) is/are withdra 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-15 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or	wn from consideration.				
Application Papers					
9)☐ The specification is objected to by the Examine 10)☑ The drawing(s) filed on 20 June 2002 is/are: a Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11)☐ The oath or declaration is objected to by the Examine 11.	a) accepted or b) objected to drawing(s) be held in abeyance. See tion is required if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority document</li> <li>2. Certified copies of the priority document</li> <li>3. Copies of the certified copies of the priority document</li> <li>* See the attached detailed Office action for a list</li> </ul>	ts have been received. ts have been received in Application trity documents have been receive u (PCT Rule 17.2(a)).	on No ed in this National Stage			
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Paper No(s)/Mail Date 9/3/02.	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	(PTO-413) te atent Application (PTO-152)			

Art Unit: 2123

#### **DETAILED ACTION**

#### Introduction

1. Claims 1-15 of U.S. Application 10/064,191, originally filed on 06/20/2002, are currently pending.

# Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

- 3. Claims 1-15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. An invention which is eligible for patenting under 35 U.S.C. § 101 is in the "useful arts" when it is a machine, manufacture, process or composition of matter, which produces a concrete, tangible, and useful result. The fundamental test for patent eligibility is thus to determine whether the claimed invention produces a "useful, concrete and tangible result." The test for practical application as applied by the examiner involves the determination of the following factors:
  - a. "<u>Useful</u>" The Supreme Court in *Diamond v. Diehr* requires that the examiner look at the claimed invention as a whole and compare any asserted utility with the claimed invention to determine whether the

Art Unit: 2123

asserted utility is accomplished. Applying utility case law the examiner will note that:

Page 3

- the utility need not be expressly recited in the claims, rather it may be inferred.
- if the utility is not asserted in the written description, then it must be well established.
- b. "Tangible" Applying In re Warmerdam, 33 F.3d 1354, 31 USPQ2d 1754 (Fed. Cir. 1994), the examiner will determine whether there is simply a mathematical construct claimed, such as a disembodied data structure and method of making it. If so, the claim involves no more than a manipulation of an abstract idea and therefore, is nonstatutory under 35 U.S.C. § 101. In Warmerdam the abstract idea of a data structure became capable of producing a useful result when it was fixed in a tangible medium which enabled its functionality to be realized. See especially MPEP §2106 (A). See especially also Schrader, 22 F.3d at 295, 30 USPQ2d at 1459.
- c. "Concrete" Another consideration is whether the invention produces a "concrete" result. Usually, this question arises when a result cannot be assured.
- 4. The Examiner respectfully submits that the final claimed steps of the invention, "analyzing an event by a [deterministic or probabilistic] methodology", do not recite either a tangible or a concrete result.

Art Unit: 2123

a. The claims are not tangible because "analyzing an event" is an abstract idea.

b. The claims are not concrete because there is no identifiable output. Since there are no results, results are not assured.

# Claim Rejections - 35 USC § 103

- 5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 6. The prior art used for these rejections is as follows:
  - a. King, T. et al. "Framework for Risk-Informed Changes to the Technical Requirements of 10 CFR 50." Draft, Revision 2. August, 2000. Cited by Applicant in the IDS filed 09/03/2002. ("Framework").
  - b. McCalley, J.D. et al. "An Overview of Risk-Based Security Assessment."
     IEEE Power Engineering Society Summer Meeting. July 1999. Vol.1.
     pp.173-178. ("McCalley").
  - c. Poulter, Susan. "Monte Carlo Simulation in Environmental Risk
     Assessment Science, Policy and Legal Issues." <u>Risk: Health, Safety & Environment</u>. Vol.9, Winter 1998.
     <a href="http://www.piercelaw.edu/risk/vol9/winter/Poulter.pdf">http://www.piercelaw.edu/risk/vol9/winter/Poulter.pdf</a>. ("Poulter").

Art Unit: 2123

d. Nuclear Energy Institute, "Nuclear Power Plant Regulation." October 2001.
 http://www.nei.org/documents/Status Report Regulation.pdf. ("NEI")

- 7. The claim rejections are hereby summarized for Applicant's convenience. The detailed rejections follow.
- 8. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Framework in view of McCalley and further in view of Poulter and NEI.
- 9. In regards to Claim 1, Framework teaches the following limitations:
  - 1. A risk-informed method for safety analyses of nuclear power generating systems, said method comprising:

ordering events by an initiating event frequency;

defining an initiating event frequency threshold value;

Examiner notes that Fig.3-1 lists three categories of event initiating frequencies: (1) frequent initiators, (2) infrequent initiators, and (3) rare initiators.

defining acceptance criteria having an adjusted amount of conservatism, wherein the amount of conservatism is a function of the initiating event frequency; and

The Framework reference teaches the use of a "safety margin" (see especially p.4-1):

The treatment of uncertainty from the design basis perspective involves the notion of safety margin. Colloquially, terms like safety margin and safety factor imply a measure of the conservatism employed in a design or process to assure a high degree of confidence that it will work to perform a needed function.

And also see especially p.4-2, right column:

Safety margin is imposed to account for uncertainties in data and models by conservatisms placed in acceptance criteria and methods for demonstrating compliance with acceptance criteria. The approach preferred for the Option 3 study is (1) to specify reasonable safety margin in acceptance criteria based on probabilistic considerations and risk insights, and (2) to use best-estimate code calculations with uncertainty propagation to demonstrate compliance based on a computed 95<sup>th</sup>

Art Unit: 2123

percentile. When this approach is precluded, an attempt will 'be made to achieve an equivalent level of safety margin in order to avoid excessive conservatism.

In regards to the following limitations,

determining if an event has an event initiating frequency at or above the threshold value;

determining if an event has an event initiating frequency below the threshold value; and

determining if a nuclear power generating system meets licensing requirements by:

analyzing an event by a deterministic safety analysis methodology when the event has an event initiating frequency at or above the threshold value; or

analyzing an event by a probabilistic risk assessment methodology when the event has an event initiating frequency below the threshold value.

The Framework reference teaches (see especially p.2-2, right column) that:

The structuralist or traditionalist model asserts that defense-in-depth is embodied in the structure of the regulations and in the design of the facilities built to comply with those regulations. ...

In contrast, the rationalist (or risk-based) model asserts that defense-indepth is the aggregate of provisions made to compensate for uncertainty and incompleteness in our knowledge of accident initiation and progression. This is made practical by the ability to quantify risk and estimate uncertainty using PRA [probabilistic risk assessment] methods.

The Framework reference further teaches (see especially p.2-3, left column, first para.) that:

The approach adopted herein recognizes the relevance of both structuralist and risk-based considerations.

However, the Framework reference does not teach any preference for either the deterministic approach or the risk-based approach.

The McCalley reference, on the other hand, expressly teaches a preference for risk-based analysis over deterministic analysis. The McCalley

Art Unit: 2123

reference teaches that a purely deterministic approach leads to overbuilding and underutilization (See p.175, Section 3 "Why Change"", para.1. Emphasis added):

The deterministic approach has served the industry well; it has provided high reliability levels without requiring excessive study effort. Yet there has been a real and tangible price to pay for using this approach: solutions tend to be overly conservative, due to the emphasis of the most severe, credible event. Consequently, existing facilities are not fully utilized, from an operating perspective, and the system becomes overbuilt, from a planning perspective.

In addition, McCalley further teaches the motivations to shift from a deterministic approach to a risk-based approach (see p.175, left column, last para.):

It is in this environment of frequent stressed system operation that the weaknesses of the deterministic approach become salient. One glaring weakness is that it is difficult to economically evaluate the security level.

Moreover, the McCalley reference further teaches that another problem with the deterministic approach is that it does not account for event frequency (See p.175, right column, emphasis added):

For some problems such as overload and voltage security, measures of event security do exist ... and these measures are used within deterministic assessment to judge security level. Yet these measures <u>do not account for event occurence frequency</u>. Application of the <u>deterministic approach accepts the implicit assumption that all events in the contingency set occur with equal frequency</u>. However, even if the contingency set includes only N-1 events, significant variation in occurrence frequently may exist.

McCalley also teaches yet another aspect of the deterministic approach (See p.175, right column):

The deterministic approach bases decisions on the performance of the most restrictive event(s). Less restrictive events have no influence on the decision.

Art Unit: 2123

In addition, McCalley teaches (See p.175, last para. to p.176, 1<sup>st</sup> para. Emphasis in original):

These [deterministic] methods were <u>acceptable</u> under the earlier industry structure because stressed operation occurred infrequently, and conservatism was embraced. These methods were perceived as <u>necessary</u> because of the difficulty in assessing uncertainty via performing increased computations or obtaining additional data.

Today, transmission and generation owners are keen on fully utilizing equipment to maximize the return on their investment in facilities. ... Simultaneously, computational speed has dramatically increased, and fast computers available today can effectively be used to probe a wider range of operating conditions and consequently reduce uncertainty.

Finally, obtaining appropriate data ... can be viewed as a decision-making problem itself, where one employs probabilistic decision paradigms for deciding whether to spend resources for gathering that data by comparing its worth to the cost of the necessary resources.

The Poulter reference, in contrast to the Framework and McCalley references, teaches that there are advantages <u>and</u> disadvantages to a risk-based approach (see p.13, last para. to p.14, first para.):

The proponents recognize that Monte Carlo [risk-based] methods have some advantages as well as advantages. They require more data ... Clearly, they require a greater level of mathematical and computer sophistication ... As with any use of a mathematical model, the results are only as good as the assumptions ... The greater complexity also presents challenges to effective risk communication and public participation in regulatory proceedings ..."

The Poulter reference also teaches that "these [Monte Carlo] methods raise many policy and legal issues which may be obscured by the complexity of the methods." (See p.26, "Conclusion").

The NEI reference presents yet another opinion regarding the relative merits of deterministic and risk-based analyses (See p.9):

Art Unit: 2123

The existing deterministic requirements, to which the plants were designed and licensed, served well in providing a robust design with a strong defense in-depth. They do not work well in pointing out where to place operational focus.

There is growing support within the industry and the NRC to move toward a risk-informed, performance-based regulatory process, made possible by the development of an analytical tool called "probabilistic safety assessment."

Therefore, the four references present different opinions as to the relative merits of deterministic and Monte Carlo methods. The Framework reference "recognizes the relevance of both structuralist and risk-based considerations". The McCalley reference finds the risk-based method to be superior to the deterministic method. The Poulter reference teaches that both methods have unique advantages and disadvantages. The Nei reference teaches that deterministic methods are preferable for plant design, while risk-based methods are preferable for design operation.

Examiner therefore finds that it was old and well known to use a risk-based method, or a deterministic method, or a combination of both methods.

Therefore, the selection of the specific combination is a matter of **design choice**.

The Framework, McCalley, Poulter, and NEI references are analogous art because they are from similar problem solving areas – nuclear reactor risk analysis (Framework, Poulter at pp.23-25, and NEI), and electrical power network risk analysis (McCalley).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the Framework reference with the McCalley, Poulter, and

Art Unit: 2123

NEI references to use deterministic and risk-based approaches under different circumstances, because all three methods expressly teach varying opinions regarding the relative merits of each method.

The motivation for combining the references would have been to determine the advantages and disadvantages of the deterministic and risk-based approaches.

Therefore, it would have been obvious to combine Framework, McCalley, Poulter, and NEI to obtain the invention as specified in claim 1.

- 10. In regards to Claim 2, Framework teaches the following limitations:
  - 2. A method in accordance with Claim 1 further comprising determining an amount of conservatism used in the deterministic safety analysis methodology, wherein the amount of conservatism is a function of the initiating event frequency.

The Framework reference teaches the use of a "safety margin" (see especially p.4-1):

The treatment of uncertainty from the design basis perspective involves the notion of safety margin. Colloquially, terms like safety margin and safety factor imply a measure of the conservatism employed in a design or process to assure a high degree of confidence that it will work to perform a needed function.

And also see especially p.4-2, right column:

Safety margin is imposed to account for uncertainties in data and models by conservatisms placed in acceptance criteria and methods for demonstrating compliance with acceptance criteria. The approach preferred for the Option 3 study is (1) to specify reasonable safety margin in acceptance criteria based on probabilistic considerations and risk insights, and (2) to use best-estimate code calculations with uncertainty propagation to demonstrate compliance based on a computed 95<sup>th</sup> percentile. When this approach is precluded, an attempt will 'be made to achieve an equivalent level of safety margin in order to avoid excessive conservatism.

11. In regards to Claim 3, Framework teaches the following limitations:

Art Unit: 2123

3. A method in accordance with Claim 2 further comprising:

identifying additional system failures that are not a direct consequence of the initiating event;

defining a total threshold frequency for the combination of the initiating event frequency and the additional failure frequency; and

adding additional system failures to the safety analysis, one at a time, until a total frequency of an event plus additional failures is less than the total threshold frequency when the initiating event frequency is above the total threshold frequency.

See especially p.3-5, left column:

The quantitative guideline is less than  $10^{-2}$ /ry for the frequency of all initiators in the infrequent category. On an industry-wide basis it is possible to monitor performance against this quantitative guideline. The quantitative guideline for the conditional probability of core damage given an infrequent initiator is  $10^{-2}$  to ensure a CDF less than  $10^{-4}$ . Based on existing PRAs the proposed quantitative guidelines provide a reasonable balance between initiator prevention and core damage prevention. The guidelines for the two mitigative strategies are again a conditional probability of a large early release of  $10^{-1}$  or less and a conditional probability of a large late release of  $10^{-1}$  or less.

For accidents in which one or more of the four high-level defense-in-depth strategies is precluded, the individual strategy guidelines may be less important than their products; that is, more emphasis needs to be placed on the strategies that remain. For example, consider a PWR interfacing-system loss-of-coolant accident (ISLOCA) in which containment is bypassed. The early containment failure probability is 1.0, therefore the quantitative guideline of 10<sup>-1</sup> cannot be achieved. Since no special ECCS is provided for ISLOCAS, there is a need to limit the relative frequency of such LOCAS and consider them in emergency planning.

# 12. In regards to Claim 4, Framework teaches the following limitations:

4. A method in accordance with Claim 2 wherein determining an amount of conservatism used in the deterministic safety analysis methodology comprises developing at least one deterministic safety analysis methodology containing a predetermined amount of conservatism based on the initiating event frequency,

wherein the predetermined amount of conservatism used in a deterministic safety analysis methodology is a function of the difference between the initiating event frequency and the initiating event frequency threshold value.

Art Unit: 2123

See the rejection of claim 2. Examiner finds this to be inherent to the definition of a "safety margin" or "margin of error".

- 13. In regards to Claim 5, Framework teaches the following limitations:
  - 5. A method in accordance with Claim 1 wherein defining acceptance criteria having an adjusted amount of conservatism comprises developing at least one acceptance criteria containing a predetermined amount of conservatism based on the initiating event frequency,

wherein the predetermined amount of conservatism for an acceptance criteria is a function of the difference between the initiating event frequency and the initiating event frequency threshold value.

See the rejection of claim 2. Examiner finds this to be inherent to the definition of a "safety margin" or "margin of error".

14. Claims 6-10 and 11-15 are rejected based on the same reasoning as claims
1-5. Claims 6-10 are system claims, and claims 11-15 are computer program
claims that recite limitations equivalent to those recited in method claims
1-5 and taught throughout Framework.

#### Response to Amendment

#### Claim Objections

- 15. Applicant has amended claims 4, 5, 9, 10, 14, and 15 to recite "predetermined amount of conservative" instead of "predetermined amount of conservatism".
- 16. Examiner has therefore withdrawn the relevant claim objections.

## Claim Rejections - 35 USC § 101

- 17. The fundamental test for patent eligibility is to determine whether the claimed invention produces a "useful, concrete and tangible result."
- 18. See <u>State Street Bank & Trust Co. v. Signature Financial Group Inc.</u>, 149 F.3d at 1373-74, 47 USPQ2d at 1601-02 (Fed. Cir. 1998) ("[T]he transformation of data,

Art Unit: 2123

representing discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price, constitutes a practical application of a mathematical algorithm, formula, or calculation, because it produces 'a useful, concrete and tangible result' – a final share price momentarily fixed for recording and reporting purposes and even accepted and relied upon by regulatory authorities and in subsequent trades").

Page 13

- 19. See also AT&T Corp. v. Excel Communications, Inc., 172 F.3d at 1358, 50

  USPQ2d at 1452 (Fed. Cir. 1999) (Claims drawn to a long-distance telephone billing process containing mathematical algorithms were held patentable subject matter because the process used the algorithm to produce a useful, concrete, tangible result a primary interexchange carrier ("PIC") indicator without preempting other uses of the mathematical principle).
- 20. Applicant unpersuasively argues (See amendment filed 4/12/06, pp.7-8) that the amendments to the independent claims overcome the 35 USC § 101 rejections.

  The Applicant "submits that the method is useful which produces a tangible and concrete result" (See Applicant's amendment, dated 4/12/06, p.8).
- 21. Examiner respectfully disagrees. The amended claims still do not recite any tangible, concrete result. While the independent claims recite a utility of "determining if a nuclear power generating system meets licensing requirements", they do not recite any concrete and useful result.

Art Unit: 2123

22. The claims also recite the use of intermediate values: "an event initiating frequency", and a "threshold value", however, neither of these is a "useful, concrete and tangible result."

23. Examiner also notes that the McCalley reference teaches (see p.175, right column, 2<sup>nd</sup> para.): "measures of event security that do exist, e.g., over-current or under-voltage, and these measures are used within deterministic assessment to judge security level."

## Claim Rejections - 35 USC § 112

24. Applicant has responded to the 35 USC § 112 rejections with the following admission:

Applicant submits that because nuclear regulatory licensing requirements are stringent and highly detailed by the Nuclear Regulatory Commission, one skilled in the art knows which events that need to be examined and analyzed to show compliance with governmental licensing requirements.

25. Examiner has found this admission to be persuasive in regards to 35 USC § 112 rejections. The 35 USC § 112 rejections have been withdrawn.

# Claim Rejections - 35 USC § 102

26. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. The new grounds of rejection address the newly-added limitations, in particular, integrating statistical and deterministic analyses.

Art Unit: 2123

### Conclusion

27. The following prior art, made of record and not relied upon, is considered pertinent to applicant's disclosure.

- 28. Gurpinar, A. et al. "Global Blueprints for Change: Living with Natural and Technological Hazards." <a href="International Workshop on Disaster Reduction">International Workshop on Disaster Reduction</a>. Aug. 19-22, 2001. <a href="http://www.gadr.giees.uncc.edu/DOCS/Theme\_A\_sent\_out/...">International Workshop on Disaster Reduction</a>. Aug. 19-22, 2001. <a href="http://www.gadr.giees.uncc.edu/DOCS/Theme\_A\_sent\_out/...">International Workshop on Disaster Reduction</a>. Aug. 19-22, 2001. <a href="http://www.gadr.giees.uncc.edu/DOCS/Theme\_A\_sent\_out/...">International Workshop on Disaster Reduction</a>. Aug. 19-22, 2001. <a href="https://www.gadr.giees.uncc.edu/DOCS/Theme\_A\_sent\_out/...">https://www.gadr.giees.uncc.edu/DOCS/Theme\_A\_sent\_out/...</a> (Teaches in the past page that "The well established methods of re-evaluation for nuclear power plants [either deterministic or probabilistic] can easily be adopted for other critical facilities.")
- 29. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

# Correspondence Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ayal I. Sharon whose telephone number is (571) 272-3714. The examiner can normally be reached on Monday through Thursday, and the first Friday of a bi-week, 8:30 am – 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paul Rodriguez can be reached at (571) 272-3753.

Any response to this office action should be faxed to (571) 273-8300, or mailed to:

USPTO P.O. Box 1450 Alexandria, VA 22313-1450

or hand carried to:

USPTO Customer Service Window Randolph Building 401 Dulany Street Alexandria, VA 22314

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center 2100 Receptionist, whose telephone number is (571) 272-2100.

Ayal I. Sharon Art Unit 2123 July 7, 2006

PAUL RODRIGUEZ
SUPERVISORY PATENT EXAMINER

TECHNOLOGY CENTER 2100